## REMARKS

### Status of the Claims

Claims 1-6 and 8-22 are currently pending in the application. Claims 1-9 stand rejected. Claims 10-19 are withdrawn as being drawn to a non-elected invention. Claims 1-6, 8-16, 18 and 19 have been amended. Claims 7 and 17 have been cancelled. All amendments and cancellations are made without prejudice or disclaimer. New claims 20-22 have been added. No new matter has been added by way of the present amendments. Specifically, the amendments to claims 1, 8 and 10 are supported by the specification at, for instance, page 7, last paragraph, and claims 7 and 17. Amendments of dependent claims 2-6, 8-16, 18 and 19 are to conform the claims more closely to US practice. Claims 8 and 18 are further amended to depend from claims 1 and 10, respectfully. New claim 20 is supported at least by original claim 1. New claim 21 is supported at least by original claim 2. New claim 22 is supported at least by original claim 12. Reconsideration is respectfully requested.

### Restriction Requirement

The Examiner has made final the Restriction Requirement of November 15, 2007. Therefore, claims 10-19 are withdrawn from further consideration as being drawn to a non-elected invention. However, claims 10-19 are maintained herein pursuant to MPEP § 821.04, which addresses the rejoinder of claims drawn to a product (claims 1-9) and their process of use (claims 10-19). That is, where Applicants elect claims directed to the product, and a product is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claims will be rejoined in accordance with the

provisions of M.P.E.P. § 821.04. Such process claims that depend from or otherwise include all the limitations of the patentable product are entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Furthermore, in the event of rejoinder, Applicants understand that the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims must be fully examined for patentability according to the provisions of 37 C.F.R. § 1.104.

**Priority**

The Examiner acknowledges the fact that the present application is the National Stage filing of International Patent Application No. PCT/EP03/08236, which was filed on July 25, 2003. Thus, the effective US filing date for the present application is July 25, 2003. However, the Examiner also states that priority cannot be claimed under 35 U.S.C. § 119(a)-(d) because "the United States application was filed more than twelve months thereafter," referring to foreign priority application DE 10235556.8, filed on August 3, 2002.

However, Applicants wish to respectfully point out that since Applicants' effective US filing date is July 25, 2003, their foreign priority application DE 10235556.8 was clearly filed within 12 months of the effective US filing date (August 3, 2002 is within 12 months of July 25, 2003). The Examiner is respectfully referred to 35 U.S.C. § 119(a) under which such foreign priority is granted in these circumstances:

> An application for patent for an invention filed in this country by any person who has, or whose legal representatives or assigns have, previously regularly filed an application for a patent for the same invention in a foreign country which affords similar privileges in the case of applications filed in the United States or to citizens of the United States, or in a WTO member country, shall have the same effect as the same application would have if filed in this

> country on the date on which the application for patent for the same invention was first filed in such foreign country, if the application in this country is filed within twelve months from the earliest date on which such foreign application was filed; but no patent shall be granted on any application for patent for an invention which had been patented or described in a printed publication in any country more than one year before the date of the actual filing of the application in this country, or which had been in public use or on sale in this country more than one year prior to such filing.

Therefore, Applicants believe they have properly requested priority under 35 U.S.C. § 119(a).

**Specification**

The Examiner objects to the Abstract of the disclosure because "it refers to non-elected subject matter." (*See*, Office Action of February 5, 2008, at page 4, hereinafter, "Office Action"). The Examiner requests correction under MPEP § 608.01(b).

The Examiner is respectfully reminded that although claims 10-19 may be presently withdrawn, Applicants have a right to Petition the issued Restriction Requirement and/or a right to reconsideration and rejoinder of withdrawn subject matter prior to allowance of the application. This is particularly true since the withdrawn claims are directed to methods which utilize the claimed products. Thus, cancellation of this subject matter from the abstract is not believed to be required at this stage in prosecution.

The Examiner further objects to the Title of the Invention. However, the Examiner provides no reasoning for this objection. Applicants believe that the present Title accurately reflects the present disclosure and claimed invention. That is, since no direction or reasoning is

provided by the Examiner explaining why the Title of the Invention is improper, Applicants are unsure how the Title of the Invention should be amended.

Reconsideration and withdrawal of the objection to the Abstract and Title of the Invention are respectfully requested.

**Rejections Under 35 U.S.C. § 112, Second Paragraph**

Claims 1, 2 and 7-9 stand rejected under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. (*See*, Office Action, at pages 5-6). Claim 7 has been cancelled, thereby obviating the rejection of claim 7. Applicants traverse the rejection as to the remaining claims.

The Examiner states that claims 1 and 9 are indefinite for reciting different limitations which follow the phrase "can be." The Examiner states that it is unclear whether these limitations are part of the invention.

The Examiner further states that the term "with galanthamine being preferred" is indefinite, as recited in claim 2. The Examiner also states that the administration forms "for solutions" recited in claim 8 are not clear.

Although Applicants do not agree that the present claims are indefinite, to expedite prosecution, the "can be" and "preferred" limitations of claims 1 and 2 have been removed and placed into new dependent claims 20-21. Claim 9 has been amended to insert "is capable of" in place of "can be."

Furthermore, claim 8 has been amended herein to remove the phrase "for solutions" and to add the phrase "in the form of" to further clarify the meaning of claim 8.

Therefore, reconsideration and withdrawal of the indefiniteness rejection of claims 1, 2, 8 and 9 are respectfully requested.

**Rejections Under 35 U.S.C. § 102(b)**

Claims 1-3 and 5-7 stand rejected under 35 U.S.C. § 102(b) as being anticipated by McGee et al., U.S. Patent No. 7,160,559 (hereinafter referred to as "McGee et al."). (*See*, Office Action, at pages 6-8). Claim 7 has been cancelled herein, thus obviating the rejection as to claim 7. Applicants traverse the rejection as to the remaining claims.

The Examiner states that McGee et al. disclose a controlled release formulation containing galanthamine as the active ingredient, wherein the formulation comprises particles of galanthamine hydrobromide and a saliva-soluble, biocompatible matrix. The Examiner states that McGee et al. disclose both a sustained release and immediate release formulation of the galanthamine particles. The Examiner cites to column 1, lines 60-67 of McGee et al. for support of transdermal administration and column 8, lines 24-25 for administration of 10-25 mg from individual dosages of galanthamine.

Although Applicants do not agree that McGee et al. anticipate the presently claimed invention, the subject matter of pending claim 7 was incorporated into pending claim 1 to specify the administration form enabling rapid entry of galanthamine into the central nervous system. In addition, the embodiment pertaining to an administration form for rapid entry of galanthamine into the central nervous system comprising a solid, biocompatible matrix that is quickly soluble in saliva was deleted.

The capsules according to McGee et al. contain pellets for rapid release of galanthamine, i.e. solid formulations. However, McGee et al. does not disclose a liquid administration form which enables a rapid entry of galanthamine into the central nervous system. Therefore, McGee et al. do not disclose all of the limitations of the presently claimed invention, which is drawn to a medicament which comprises a buccal solution, a spray solution or a drip solution for combating cravings for alcohol and/or nicotine despite use of a basal pharmaceutical withdrawal therapy. Anticipation requires that "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (*See*, *In re Robertson*, 169 F.3d 743, 745, 49 U.S.P.Q.2d 1949 (Fed. Cir. 1990), quoting *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987)).

McGee et al. disclose a pharmaceutical preparation in the form of a single administration dosage, namely a capsule. The capsule of McGee et al. contains particles for controlled drug release and particles for faster drug release. However, both kinds of particles are contained in a capsule, which is the administration form, i.e. the preparation that is administered to the patient.

The McGee et al. capsule is orally administered and the different particles contained therein are released into the gastrointestinal tract after said capsule has been swallowed. Within the gastrointestinal tract, the drug is immediately released from one of the two kinds of particles and slowly released from the other of the two kinds of particles. However, the drug has to be absorbed through the intestinal mucosa to enter the patient's circulation. Such a process is not considered to be an administration for a rapid entry of said drug into the central nervous system.

Claim 1 specifies that the two administration forms are not the same, i.e. are of different form. This concept is further emphasized in amended claim 1, wherein the administration form

for enabling a quick entry of galanthamine is specified. McGee et al. do not disclose this limitation, as previously recited in claim 7 (now cancelled) and which is now recited in amended claim 1. McGee et al. merely disclose a single administration form (a capsule) which contains drug preparations for continuous and immediate release.

Even if the drug preparations for continuous release and for immediate release according to McGee et al. would be considered to be two different "administration forms," it is clear that the two administration forms are both in the physical form of a capsule.

Although the drug preparations for continuous release are referred to as "CR pellets" in McGee et al., and the drug preparation for immediate release is referred to either as "IR topcoat" or "IR minitablet," both the "CR pellets" and the "IR topcoat" are coated 18-20 mesh sugar spheres. Even if the "IR minitablets" are not coated, their manufacturing results in drug-containing pellets that are filled into a capsule in the same manner as the "CR pellets." Regardless of whether the drug-containing preparations are referred to as "pellets" or as "minitablets," the preparations do not differ in their physical form in which they are ultimately administered, i.e. a solid capsule. Hence, they do not represent different forms or means for administering the drug as recited in presently amended claim 1.

Dependent claims 2, 8 and 9 are not anticipated as, *inter alia*, depending from a non-anticipated base claim, claim 1.

Reconsideration and withdrawal of the anticipation rejection of claims 1, 2, 8 and 9 are respectfully requested.

**Rejections Under 35 U.S.C. § 103(a)**

Claims 1-9 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over McGee et al. in view of Plata-Salaman, U.S. Patent Application Publication No. 2003/0060423 (hereinafter, "Plata-Salaman"). (*See*, Office Action, at pages 8-11). Claim 7 has been cancelled herein, thus obviating the rejection as to claim 7. Applicants traverse the rejection as to the remaining claims.

In addition to the comments above, the Examiner admits that McGee et al. neither disclose nor suggest the specific release ranges of 10-25 mg of galanthamine and/or 5-50 mg of nicotine. The Examiner also admits that McGee et al. do not disclose or suggest a flexible plastic container having a 1-5 mL capacity with nozzles.

*Graham v. John Deere*, 383 U.S. 1, 17, 148 U.S.P.Q. 459, 467 (1966) has provided the controlling framework for an obviousness analysis. A proper analysis under 35 U.S.C. § 103(a) requires consideration of the four *Graham* factors of: (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims that are at issue; (3) resolving the level of ordinary skill in the pertinent art; and (4) evaluating any evidence of secondary considerations (e.g., commercial success; unexpected results). (*See*, *Graham v. John Deere*, 383 U.S. at 17, 148 U.S.P.Q. at 467).

Applicants have provided comments, above, summarizing the pertinent disclosure of McGee et al. and the differences between the presently claimed invention and the disclosure of McGee et al. Applicants also assert that the disclosure of Plata-Salaman fails to cure the defective disclosure of McGee et al. That is, in addition to the comments already provided above, with respect to the anticipation rejection over the disclosure of McGee et al., Applicants

provide the following comments distinguishing the secondary reference of Plata-Salaman from the presently claimed invention.

The secondary reference, Plata-Salaman, does not pertain to the treatment of cravings for alcohol and/or nicotine, but instead is directed to the treatment of dementia or memory disorders. These disorders are unrelated to cravings for alcohol and/or nicotine. Thus, there would be no reason to combine these two unrelated references, nor any expectation of success upon doing so. That is, Plata-Salaman teaches co-administration of an anti-cholinergic drug and an anti-convulsant in the therapy of dementia or memory disorders. In contradistinction, the medicament of the presently claimed invention does not comprise an anti-convulsant.

For this reason, it is doubtful that one of ordinary skill in the art would consider Plata-Salaman as relevant to the problem addressed by the presently claimed invention, which is related to providing a pharmacological withdrawal therapy medicament that efficiently combats the breakthrough cravings for alcohol and/or nicotine, which occur despite an ongoing basal pharmacological withdrawal therapy.

Furthermore, the presently claimed invention is based on the surprising observation that galanthamine, if administered in a form which rapidly enters the brain, can be used for preventing or treating the breakthrough craving for alcohol and/or tobacco products in patients addicted to these substances. According to the presently claimed invention, an administration form providing rapid entry of galanthamine is combined with another administration form which continuously releases a modulator of nicotinic receptors (e. g. nicotine or galanthamine) and which thus provides a long-term, or basic, withdrawal therapy.

It has not yet been reported in the prior art that breakthrough cravings for alcohol and/or tobacco products can be treated by supplemental administration of galanthamine or a pharmaceutically acceptable salt thereof if the patient undergoes pharmaceutical withdrawal therapy, and if the supplemental dose of galanthamine or a pharmaceutically acceptable salt thereof is administered such that said galanthamine or salt thereof rapidly enters the central nervous system of the patient. That is, it is not disclosed or suggested anywhere in the prior art that combining a pharmaceutical composition for continuous release of galanthamine, nicotine, or a pharmaceutically acceptable salt thereof, with a medicament that enables rapid entry of galanthamine or a pharmaceutically acceptable salt thereof into the patient's central nervous system, would be an effective medicament for treating addiction craving.

Neither McGee et al., nor Plata-Salaman address the problem of treating breakthrough cravings nor provide any suggestion to one of ordinary skill in the art that would provide a reason to consider the possible success of the presently claimed medicament, such that the person of ordinary skill in the art would modify the medicaments that may be disclosed in the cited prior art references to arrive at the subject matter of the presently claimed invention.

Therefore, reconsideration and withdrawal of the obviousness rejection of claims 1-6, 8 and 9 are respectfully requested.

## CONCLUSION

If the Examiner has any questions or comments, please contact Thomas J. Siepmann, Ph.D., Registration No 57,374, at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

By _____

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